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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,435	01/22/2004	Pablo Umana	1975.0180003/TJS	3728

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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,435	UMANA ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-286* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-286* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please not the Examiner and the art unit has changed. The Examiner is now Michael Burkhart and the art unit is 1633.

Applicants' response filed August 14, 2006, and election of Group III (claims 30-34, 65-95, 128, 129, 186-212 and 216-260) is noted. However, upon reconsideration of the claims and the previous restriction requirement, a new restriction requirement is being made.

Claims 20, 30, 96, 97, 108-112, 115, 116 have been amended. Claims 1-286 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 28, 29, 35-64, 119-122, 126, 127, 130-185, and 285 are drawn to an isolated nucleic acid, vectors and method of expression comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyl transferase activity and comprises the Golgi localization domain of a Golgi resident polypeptide, classified in class 435, subclass 193.

II Claims 21-27, 123-125, and 286 are drawn to a fusion polypeptide having β (1,4)-N- acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity and comprising the Golgi localization domain of a heterologous Golgi resident polypeptide, classified in class 435, subclass 193.

III Claims 30-34, 65-95, 128, 129, 186-212, and 216-227 are drawn to a method for modifying the glycosylation profile of a polypeptide produced by a host cell, comprising introducing into said host cell the nucleic acid comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity classified in class 435, subclass 455.

IV Claims 96-114, 213, 214, and 261-279 are drawn to an antibody engineered to have increased effector function produced by the method comprising introducing into said host cell the nucleic acid comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N-acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity classified in class 435, subclass 188.

V Claims 115-118, 215, and 280-284 are drawn to a method for the treatment of disease such as cancer comprising administering a therapeutically effective amount of a pharmaceutical composition comprising an antibody engineered to have increased effector function produced by the method comprising introducing the nucleic acid comprising a sequence encoding a fusion polypeptide, wherein said fusion polypeptide has β (1,4)-N- acetylglucosaminyltransferase III activity or β (1,4)-galactosyltransferase activity into a host cell classified in class 424, subclass 130.1.

VI Claims 228-260 are drawn to a method for producing a polypeptide in a host cell, comprising culturing a host cell engineered to express a sequence encoding a polypeptide with α-mannosidase II activity, classified in class 435, subclass 455.

In addition, with the election of any groups I-V above, an additional election of either β (1,4)-N- acetylglucosaminyltransferase III activity or β(1,4)-galactosyltransferase activity is required. In this case, each of the groups recite and comprise two materially different enzymes. Independent claims reciting both β (1,4)-N- acetylglucosaminyltransferase III activity or β(1,4)-galactosyltransferase activity link(s) the inventions comprised in groups I -V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the nucleic acids of Group I and the protein of Group II each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The nucleic acids of Group I comprise a nucleotide sequence and the proteins of Group II comprise unrelated amino acid sequences. The nucleic acids have other utilities besides encoding the protein, such as hybridization probe. The proteins of Group II can be made by methods that do not utilize the nucleic acids of Group I, such as isolation from natural sources or chemical synthesis.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the glycosylation profile of a polypeptide can be modified using vectors comprising genes encoding other glycosyltransferases.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the nucleic acids of Group I and the antibodies of Group II each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The nucleic acids of Group I comprise a nucleotide sequence and the antibodies of Group IV comprise unrelated amino acid sequences. The nucleic acids have other utilities besides encoding the antibodies, such as hybridization probe. The antibodies of

Group IV can be made by methods that do not utilize the nucleic acids of Group I, such as isolation from natural sources, such as CHO cell glycosylation mutants.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions group I is drawn to nucleic acid sequences and Group V is drawn to a method of treating a disease which does not require the polynucleotide cannot be used together with the antibody in the treatment method.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, group II is drawn to polypeptide sequence and Group III drawn to a method of modifying the glycosylation profile of a polypeptide using a vector comprising a polynucleotide sequence, thus the fusion polypeptide is not used in the host cell. Rather, it is the nucleic acid of Group I that is used.

Inventions in group II are unrelated to group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally and functionally different polypeptides (e.g. Group II is a fusion protein enzyme with catalytic activity whereas Group IV is directed to antibodies). Therefore, the polypeptides of Groups II and IV have different modes of operation, functions, and effects.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group II is drawn to polypeptide sequences not used in the methods of treatment found in Group V.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(0). In the instant case the process can be used to make glycosylated products other than the modified antibody of invention IV.

Inventions of Groups III and V are independent as they comprise different steps, utilize different products and/or yield different results. In addition the search and examination of each method in Groups III and V in one patent application would result in undue burden, since the searches for all the groups are not co-extensive, since the searches are in different classifications, and thus involve different fields of search. Each of the of the inventions requires a separate patent and non-patent literature search requiring a different text search for each group and thus co-examination of the inventions in groups III and V would be a serious burden on the examiner.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP §

806.05(h). In the instant case other compounds can be used in a method of treatment that do not require the antibodies of Group IV.

Inventions I-V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions utilize different enzymes with different functions (i.e. GalT or GnTIII in Groups I-V versus α-mannosidase II in Group VI) that are encoded by different nucleic acids. Any antibodies produced by the methods of Group III will be have a different glycosylation profile (and thus a different effector function according to the specification) from those produced in Group VI. The methods of Group VI are not directed towards the treatment of any disease, as found in Group V, and thus are unrelated in active steps, function, and effect.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), and because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

It is noted that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.1 16; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR l .104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Additionally, if any specific group is elected it is noted that this application contains claims directed to the following patentably distinct species:

1. Golgi localization signal (claims 3, 5, 7, for example)

2. consequence of expression on host cell (claims 48-57 or 74-81, 83, and 84, for example)

3. additional glycosylation enzyme(s) (e.g. as found in claims 130, 141, 147, 158, 174-175, 186, 187, 196, 197, 216, 220).

The species are independent or distinct because each represents a materially different product, and require separate search and consideration. Currently, Groups I-V encompass species 1 and 2, Group VI encompasses species 2, and Groups I and III encompass species 3, as listed above.

If any group is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims within a group listing the specific species are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633

Joe Woitach
AU1633